(19) World Intellectual Property Organization International Bureau



(43) International Publication Date 13 September 2001 (13.09.2001)

PCT

(10) International Publication Number WO 01/66190 A2

(51) International Patent Classification7:

A61P

(21) International Application Number: PCT/US01/06958

(22) International Filing Date: 2 March 2001 (02.03.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data: 09/519,735 4 March 2000 (04.03.2000)

(71) Applicant: EMPHASYS MEDICAL, INC. [US/US]; 2686 Middlefield Road, Suite A, Redwood City, CA 94063 (US).

(72) Inventors: DEEM, Mark; 216B Palo Alto Avenue, Mountain View, CA 94041 (US). ANDREAS, Bernard; 633 California Way, Redwood City, CA 94062 (US). CHEW, Sunmi; 1599 Martin Avenue, San Jose, CA 95126 (US). FIELDS, Antony; 87 Vicksburg Street, San Francisco, CA 94114 (US). FRENCH, Ronald; 1564 Heatherdale Avenue, Santa Clara, CA 95050 (US). GIFFORD, Hanson; 3180 Woodside Road, Woodside, CA 94062 (US). HUNDERTMARK, Ronald; 422 Alder Lane, San Mateo, CA 94403 (US). RAPACKI, Alan; 2725 Hastings Avenue, Redwood City, CA 94061 (US). SUTTON, Douglas; 1595 Adobe Drive, Pacifica, CA 94044 (US). WILSON, Peter; 1105 Emerald Bay Lane, Foster City, CA 94404 (US).

- (74) Agent: VON MORZE, Herwig; Heller Ehrman White & McAuliffe, 375 Middlefield Road, Menlo Park, CA 94025-3506 (US).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHODS AND DEVICES FOR USE IN PERFORMING PULMONARY PROCEDURES

(57) Abstract: An implantable flow control element is provided which prevents air from entering an isolated portion of a patient's lung. The element may permit air to escape from the isolated portion so that the element acts like a valve. Systems for implanting pulmonary devices are also provided.



METHODS AND DEVICES FOR USE IN PERFORMING PULMONARY PROCEDURES

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of Application No. 09/519,735 filed

March 4, 2000 entitled "Methods and Devices for use in Performing Pulmonary Procedures"
by inventors Deem et al., the full disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

10

15

20

25

30

The present invention relates generally to methods and devices for use in performing pulmonary procedures, and more particularly, procedures for treating various diseases of the lungs.

2. Description of the Background Art

Pulmonary diseases such as emphysema and chronic obstructive pulmonary disease (COPD) reduce the ability of one or both lungs to fully expel air during the exhalation phase of the breathing cycle. The diseased lung tissue is less elastic than healthy lung tissue, which is one factor that prevents full exhalation of air. During breathing, the diseased portion of the lung does not fully recoil due to the tissue being less elastic. Consequently, the diseased (e.g., emphysematic) lung tissue exerts a relatively low driving force, which results in the diseased lung expelling less air volume than a healthy lung. The reduced air volume exerts less force on the airway which allows the airway to close before all air has been expelled, another factor that prevents full exhalation.

The problem is further compounded by the diseased, less elastic tissue that surrounds the very narrow airways that lead to the alveoli (the air sacs where oxygen-carbon dioxide exchange occurs). This tissue has less tone than healthy tissue and is typically unable to maintain the narrow airways open until the end of the exhalation cycle. This traps air in the lungs and exacerbates the already-inefficient breathing cycle. The trapped air causes the tissue to become hyper-expanded and no longer able to effect efficient oxygen-carbon dioxide exchange. Applying suction to these narrow airways (a procedure proposed in the literature for deflating the diseased portion of the lung) may collapse the airways due to the surrounding diseased tissue, thereby preventing successful fluid removal.

In addition, hyper-expanded lung tissue occupies more of the pleural space than healthy lung tissue. In most cases, a portion of the lung is diseased while the remaining

Issues under 35 U.S.C. § 112, Second Paragraph

Claims 1-10 stand rejected under 35 U.S.C. § 112, second paragraph, for several reasons of asserted indefiniteness (see pages 2-3 of the Office Action). Applicants respectfully traverse, and reconsideration and withdrawal of this rejection are respectfully requested.

With regard to line 15 of instantly pending claim 1, Applicants respectfully submit that "elastic members" is recited, which properly refers to the elastic members appearing in line 10 of claim 1.

Regarding line 7 of pending claim 1, Applicants respectfully submit that this line refers to the skin-contacting surface portion. In contrast, line 18 of claim 1 does recite the folded back portion (for the first time), and also refers to the two sheet materials that constitute the three-dimensional guard.

Thus, Applicants respectfully submit that one of skill in art can read the instantly pending claims, especially in view of Applicants' written disclosure and Figures therein, and understand what is being claimed. The presented claims recite clear and definite claim language so that the skilled artisan understands the structure being claimed. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Issues under 35 U.S.C. § 102(e)

Claims 1, 2, 6 and 10 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Yoshioka '023 (U.S. Patent No. 6,156,023) (as stated on pages 3-5 of the Office Action).

Also, claims 7 and 9 stand rejected under 35 U.S.C. § 102(b) as being anticipated by in view of Toyodo et al. '571 (WO 97/12571) (see pages 5-6 of the Office Action).

Applicants respectfully traverse both rejections, and reconsideration and withdrawal thereof are respectfully requested.

Yoshioka '023 Fails to Disclosed All Claimed Structural Features

Essentially, the Examiner is maintaining that Figure 3 of the Yoshioka '023 reference still discloses the present invention. Also mentioned during the recent Interview, the Examiner stated that the presently claimed term of "portion" refers to "any part of a whole" (as stated in the Interview Summary).

However, Applicants respectfully refer the Examiner to page 4, lines 19-28 of the present specification. At this part of the specification, Applicants describe how skin-contacting portion 5A is folded back at a part of the location of the elastic member 54c nearest to the raised portion **5B** (see also Fig. 2 to visualize how the portions define the three-dimensional guard). Further, page 4, lines 7-9 describes that the skin-contacting surface portion 5A is formed by folding back a side portion on a free end 53 side toward the outer side of the diaper 1. Thus, the term "portion" in "skin-contacting surface portion" refers to the area having the continuous sheet (that wraps around free end 53 to make top and bottom sheets), and not just a part of the continuous sheet.

As another example, in discussing how the stress of the skin-contacting portion 5A is higher than the stress of the raised portion 5B (see Applicants' specification at page 6, lines 15-27, in particular lines 24-27), the stress refers to the entire area or portion 5A versus the entire area/portion 5B. One of skill in the art would understand that the stress characteristics as discussed in the present specification do not refer to, e.g., just one point within the skin-

contacting surface portion 5A (see also how the stress is tested in the specification at page 7. starting at line 26, which refers to portions).

Applicants further note that instantly pending claim 1 recites that "said elastic members in the said second set in the raised portion is fixed between two sheet materials, wherein said two sheet materials form the three-dimensional guard." Thus, the raised portion, which is a part of the three-dimensional guard, has two sheet materials that surround the internal elastic members. Further, the skin-contacting surface portion is "formed by folding back a side on a free side towards an outer side of said absorbent article" and "is located more on a free end side than the folded back portion, and the region of the guard widthwise ranging from the folded back portion to the free end forms the skin-contacting surface portion" (see pending claim 1 as presented herein). Thus, the instantly claimed portions are not defined as "any part of a whole."

Further, Fig. 1 of this application shows a back side portion A as well as the other back side portion B. One of skill in the art, upon reviewing Fig. 1, would understand that "portion" of back side portion A refers to an area, and not just, e.g., sheet material 91 or just elastic members 92. Applicants respectfully submit that the term "portion" is not defined as "any part of a whole." Instead, the instantly claimed three-dimensional guard has a skin-contacting portion, a raised portion, and a folded portion in between.

Thus, the instant rejection has been overcome based on the present claim language. Specifically, regarding the term "portion," and in maintaining the rejection, the Examiner defines the area between elastic members 24B and the first 24C in the Yoshioka '023 Fig. 3 to be the skin contacting surface portion, and the area between elastic members of the second 24C and 24A in Fig. 3 to be the raised portion. However, this would mean that matching the instantly claimed folded portion would be in between the first 24C and the second 24C of Yoshioka '023. Specifically, instantly pending claim 1 recites that the three-dimensional guard is formed by: "a skin-contacting surface portion formed by folding back a side on a free side towards an outer side of said absorbent article." Further, claim 1 of this application recites the location of the

folded back portion as being: "located between the skin-contacting surface portion and said

raised portion." Therefore, in the present invention, the folded back portion is between the skin-

contacting and raised portions, and the three-dimensional guard is formed by folding back the

free side of the skin-contacting portion.

Regarding Yoshioka '023, Applicants further note the following description at column 4, lines 7-17:

The outer edge 27 of the sealing surface section 20 as the important part of the risen barrier cuff 19 comes in contact with a wearer's leg indicated by imaginary lines as the diaper is put on the wearer's body. With the outer side edge 27 being more tightly placed around the wearer's leg, the sealing surface zone 20 swings in a direction indicated by an arrow X around the first elastic member 24A having the highest elongation stress and, as indicated by imaginary lines, is placed against the wearer's leg 32' over its circumferential area as large as possible, whereupon the pocket 31 is opened as largely as possible.

Thus, as apparent from this excerpt in Yoshioka '023, one of ordinary skill in the art would understand that this cited reference discloses that the entire seal surface section 20 can be considered to correspond to the skin contacting surface portion of the present invention. That is, in Yoshioka '023, the elastic members 24A, 24C, 24C and 24B in Figure 3 are disposed in the area corresponding to the skin contacting portion of the present invention, and such elastic

Thus, in relation to Fig. 3 of Yoshioka '023, which is relied upon by the Examiner to reject the pending claims, the folded back portion of the reference does not correspond to or match what is instantly claimed. As mentioned briefly above, Yoshioka '023 fails to disclose the specific location as well as the formation of the folded back portion of the present invention. Accordingly, Applicants respectfully submit that Yoshioka '023 is structurally different from the present invention and this rejection has been overcome. Because "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference," the rejection in view of the cited Yoshioka '023 reference has been overcome. See Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Further, Applicants respectfully maintain that the cited Yoshioka '023 reference discloses that its members 24A, 24B and 24C are simultaneously contacting its skin contacting and raised portions. This is in contrast to the separate set of elastic members as instantly claimed (different elastic members for each of skin-contacting portion and raised portion). Further, the claim language of "wherein said raised portion is located between said skin-contacting surface portion and a base end of said three-dimensional guard" physically separates the two sets of elastic members. Thus, Applicants respectfully submit that the present invention is structurally and patentably distinct from Yoshioka '023, including Figure 3 of the cited reference.

Based on the above, Applicants respectfully submit that the rejection in view of Yoshioka '023 has been overcome. Reconsideration and withdrawal of this rejection are respectfully requested.

Toyodo '571 Fails to Disclosed All Claimed Structural Features

In rejecting pending claims 7 and 9, the Examiner states that that "elastic members are not required for each portion" (Examiner's emphasis added) (at page 6, lines 5-6 of the Office Action). However, Applicants respectfully submit that the present invention does use elastic members for each of the skin-contacting and raised portions. As can be seen from claim 7, the present invention is directed to "the elastic members in the skin-contacting surface portion of the three-dimensional guard are disposed at a smaller interval relative to the elastic members in the raised portion" (Applicants' emphasis added). Applicants note the claim 9 depends on claim 7. Therefore, in this regard, each of Figures 1, 4, 6, 7 and 9 of the cited Toyoda '571 reference fails to disclose all claimed features, including how the elastic members in the skin-contacting portion are at smaller intervals than those elastic members in the raised portion. Thus, the rejection in view of Toyoda '571 has been overcome since the cited references fails to disclose all features as recited in claims 7 and 9. *Verdegaal Bros.*, *supra*. Reconsideration and withdrawal of this rejection are respectfully requested.

Issues under 35 U.S.C. § 103(a)

Claims 3-5 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Yoshioka '023 (as stated on page 7 of the Office Action). Applicants respectfully traverse, and

reconsideration and withdrawal of this rejection are respectfully requested. Overall, Applicants do not concede that a *prima facie* case of obviousness has been established.

Lack of Disclosure of All Claims Features

Applicants respectfully submit that a prima facie case of obviousness has not been formed with respect to the asserted modification of Yoshioka '023, because not all requirements for a prima facie case of obviousness have been satisfied. In particular, there is no disclosure of all claimed features as mentioned above. Each of disputed claims 3-5 depends on claim 1, wherein claim 1 is directed to using the two sets of elastic members. Thus, Applicants submit that this rejection under § 103(a) has been overcome, since U.S. case law squarely holds that a proper obviousness inquiry requires consideration of three factors: (1) the prior art reference (or references when combined) must teach or suggest all the claim limitations; (2) whether or not the prior art would have taught, motivated, or suggested to those of ordinary skill in the art that they should make the claimed invention (or practice the invention in case of a claimed method or process); and (3) whether the prior art establishes that in making the claimed invention (or practicing the invention in case of a claimed method or process), there would have been a reasonable expectation of success. See In re Vaeck, 947 F.2d, 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991); see also In re Kotzab, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000); In re Fine, 5 USPO2d 1596 (Fed. Cir. 1988). Here, not even the first requirement of disclosure of all claimed features has been satisfied, since the cited Yoshioka '023 reference does not disclose the formation and location of the instantly claimed folded portion (e.g., between the skin contacting portion and the raised portion).

Thus, Applicants respectfully submit that a prima facie case of obviousness has not been established since not all requirements thereof have been satisfied and that this rejection has been overcome. Withdrawal of this rejection is respectfully requested.

Inoperability: Lack of Motivation and/or Reasonable Expectation of Success

Applicants also submit that the other requirements of the requisite motivation and/or reasonable expectation of success for a prima facie case of obviousness have not been satisfied. Applicants further note that the initial burden of establishing a *prima facie* case of obviousness lies with the examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); In re Piasecki, 745 F.2d 1468, 1471-72, 223 USPQ 785, 787-88 (Fed. Cir. 1984). That burden has not been met here as explained below.

First, Applicants submit that the disclosure in Yoshioka '023 is in contrast to the instantly claimed invention which employs the two sets of elastic members.

Second, Yoshioka '023 requires that its elastic members 24 be in contact with sealing surface zone 20 and simultaneously in contact with sections 17, 18 and 16 (see its Figure 3 and column 3, lines 13-22).

Thus, the rejection in view of Yoshioka '023 (as modified in the Office Action) has been overcome. This is because the claimed combination cannot change the principle of operation of the primary reference or render the reference inoperable for its intended purpose. See M.P.E.P. §§ 2143.01 (see sections entitled "The Proposed Modification Cannot Render the Prior Art Unsatisfactory For Its Intended Purpose" and "The Proposed Modification Cannot Change the Principle of Operation of a Reference") and M.P.E.P. § 2145(III); see also re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Here, the intended purpose of Yoshioka '023 is to provide the better sealing surface zone 20 that includes the overhand section 17 and the second overhang section 18 (see, e.g., column 1, lines 16-24 and column 2, lines 52-59). To match the present invention, the overhand section 18 of Fig. 3 of Yoshioka '023 would have be folded between the two elastic members 24C (these features are described in the '023 specification at, e.g., column 3, lines 13+). One of ordinary skill in the art would understand that folding the middle section of overhand section 18 would defeat the intended purpose of the Yoshioka '023 embodiment. Applicants further note that Fig. 3 shows a shadow of how overhang sections 17 and 18 is suppose to be bent upon usage (section 18 would bend down and to the left, 17 to the right and up). Thus, the Yoshioka '023 reference would be rendered inoperable for its intended purpose and the requisite motivation is lacking for the instant rejection. Alternatively, the principle operation of Yoshioka '023 would be destroyed for the reasons stated above. Accordingly, this rejection has been overcome.

Further, the requisite motivation and/or reasonable expectation of success are lacking since one of ordinary skill in the art would not reasonably expect to be successful, upon reading Yoshioka '023, in achieving the presently claimed invention when that skilled artisan has to change the overhand sections of the Yoshioka '023 embodiment (as explained above). Applicants respectfully submit that it is not *prima facie* obvious to modify a reference unless the references suggest an advantage to be gained from the modification. *See In re Sernaker*, 217 USPQ 1, 6 (Fed. Cir. 1983). Yoshioka '023 discloses not such advantage to bending overhang section 18 to match what is instantly claimed. If anything, the function of overhang sections 17 and 18 in Yoshioka '023 are that these sections are suppose to be bent upon usage (wherein

section 18 would bend down and to the left, 17 to the right and up based upon the shadowed part

in Fig. 3), and not be folded in between. Thus, Applicants submit that the requisite motivation

and/or requisite reasonable expectation of success is further lacking.

Moreover, the cited references must suggest the desirability of the modification. In re

Brouwer, 37 USPQ2d 1663, 1666 (Fed. Cir. 1995). The cited Yoshioka '023 reference does not

suggest any advantage to be gained by making the Examiner's proposed combination. Thus,

this is an additional reason as to why this rejection has been overcome.

Accordingly, Applicants respectfully submit that the instant rejection under § 103(a) has

been overcome. Reconsideration and withdrawal of this rejection are respectfully requested.

Conclusion

A full and complete response has been made to all issues as cited in the Office Action.

Applicants have taken substantial steps in efforts to advance prosecution of the present

application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the

present case.

Should there be any outstanding matters that need to be resolved in the present

application, the Examiner is respectfully requested to contact Eugene T. Perez (Reg. No. 48,501)

at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Dated:

JAN 3 0 2006

Respectfully submitted,

By_____/ John/W. Bailey

Registration No.: 32,881

BIRCH, STEWART, KOLASCH & BIRCH, LLP

Docket No.: 0445-0316P

8110 Gatehouse Road

Suite 100 East P.O. Box 747

Falls Church, Virginia 22040-0747

(703) 205-8000

Attorney for Applicant